

**MAR 13 2019**

The Honorable Ron Wyden
Ranking Member
U.S. Senate Committee on Finance
Washington, DC 20510

Dear Ranking Member Wyden:

On behalf of the Secretary of Health and Human Services, Alex M. Azar II, thank you for your letter regarding the Pain Management Best Practices Inter-Agency Task Force (Task Force). Given my role as the Secretary's Senior Advisor for Opioid Policy and because the Task Force is managed and supported by my office, the Office of the Assistant Secretary for Health (OASH), the Secretary asked that I respond on his behalf.

As you know, the Task Force was established under Section 101 of the Comprehensive Addiction and Recovery Act of 2016 (CARA) to develop recommendations on clinical best practices for managing chronic and acute pain. CARA requires the Task Force be comprised of a wide spectrum of stakeholders, including representatives of pain management professional organizations, pain advocacy groups, hospitals, and others. The Task Force is a federal advisory committee that provides independent advice and follows applicable Federal Advisory Committee Act (FACA) law to ensure that the advisory committee's advice and recommendations will not be inappropriately influenced by the appointing authority or by any special interest group, but will instead be the result of the advisory committee's independent judgment.

The Department of Health and Human Services (HHS) is and has been committed to an open and transparent process in regards to the Task Force. The Task Force's charter, membership, and full meetings can viewed here: (<https://www.hhs.gov/ash/advisory-committees/pain/index.html>). A Federal Register Notice, dated August 14, 2018, announced the second Task Force meeting in which the draft recommendations were presented, deliberated, and voted on. The draft recommendations were approved by an overwhelming majority of the Task Force and the draft recommendations, along with a more thorough preliminary report, were posted for public comment on the Federal Register on December 28, 2018. The preliminary report, which had not been released at the time of your letter, can be found here: <https://www.hhs.gov/ash/advisory-committees/pain/reports/2018-12-draft-report-on-updates-gaps-inconsistencies-recommendations/index.html>. The 90-day public comment period on the draft recommendations and report closes on April 1, 2019. Following the period of public comment, the Task Force will review and consider the comments received.

Additionally, part of HHS' commitment and responsibility with this FACA is to be aware of and resolve any potential conflict(s) of interest, including among statutorily required representative members, throughout this process. The Task Force, like all FACAs, allows government decision-makers to receive informed, collaborative guidance from non-government stakeholders,

independent experts, and regular government employees (RGEs) following the robust and open dialogue of participants. There are two types of FACA members: government employees and organizational representatives. Government employees include RGEs and special government employees (SGEs), who serve the federal government for a limited purpose and a limited number of days. Most independent experts are classified as SGEs. All government employees, RGEs and SGEs alike, have a fiduciary responsibility to the federal government while working on the FACA and must follow the comprehensive federal ethics laws, including the criminal conflict of interest and financial disclosure reporting laws, and the standards of ethical conduct. In contrast, organizational representative members are not government employees. Rather, they represent the interests and viewpoint of private stakeholders (companies, unions, associations, etc.) and, therefore, are not covered by the same federal ethics laws.

CARA mandated the Task Force include representatives of multiple stakeholders and interests, including representatives of addiction and mental health treatment communities, pain management professional organizations, hospitals, and pain advocacy groups. To fulfill this statutory mandate, HHS published a Federal Register Notice, dated August 28, 2017, requesting nominations. Applications were reviewed and candidates were selected based on the criteria for membership set forth in section 101(c) of the CARA. FACA regulations were followed throughout this process to ensure that the membership would be fairly balanced in terms of views represented and the Task Force's function. The qualifications of selected candidates were further reviewed as part of the normal approval process. A conflict of interest review was conducted and conflicts were resolved in accordance with the robust federal ethics laws consistent with FACA rules and regulations. Upon conclusion of those actions, the Task Force's membership was finalized and consists of 29 individuals, including eight RGEs, twelve SGEs, and nine organizational representatives. Attached is a table that describes how each Task Force member fulfills the requirements for Task Force membership, as established by CARA. The Task Force website also lists each member by type (*i.e.*, regular government employee, special government employee, and organizational representative) and the member's primary employment organization; and for organizational representative members, the organization being represented.

One of HHS' top priorities is addressing the current opioid crisis through its five-point strategy: (1) better addiction prevention, treatment, and recovery services; (2) better data; (3) better pain management; (4) better targeting of overdose reversing drugs; and (5) better research. Better pain management to decrease the inappropriate use of opioids is essential to ending the opioid epidemic. HHS has numerous ongoing efforts to promote healthy, evidence-based methods of pain management and reduce opioid use. More information on these efforts can be found here: <https://www.hhs.gov/opioids/about-the-epidemic/hhs-response/better-pain-management/index.html>. Through these comprehensive efforts, along with the critical work of states, communities, and private stakeholders, opioid prescriptions have decreased by 21.9% since January 2017 and we must continue this progress. HHS will also continue to support and

disseminate the Centers for Disease Control and Prevention Guidelines for Prescribing Opioids for Chronic Pain, with the recognition that every patient must be cared for individually to meet our goal of reducing opioid prescribing by 30 percent over the next several years, as outlined by the President.

If you or your staff have any additional comments or concerns, I would encourage you to participate in the public comment period by providing feedback to the Task Force directly at paintaskforce@hhs.gov or through the Federal eRulemaking Portal at <http://www.regulations.gov>, docket number: HHS-OS-2018-0027. Additional questions may also be directed to Matthew Bassett, Assistant Secretary for Legislation, at (202) 690-6787.

Thank you again for your letter and your interest in this critical public health issue.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Brett P. Giroir", followed by a horizontal line and a small flourish.

Brett P. Giroir, M.D.
ADM, USPHS
Assistant Secretary for Health
Senior Advisor for Opioid Policy